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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/733,878	12/10/2003	Jean-Philippe Girard	BIOBANK.012A	8136

20995 7590 12/21/2005

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EXAMINER	
HAMA, JOANNE	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 12/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/733,878	GIRARD ET AL.	
	Examiner	Art Unit	
	Joanne Hama, Ph.D.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-212* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-212* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

This Application was filed December 10, 2003 and claims priority to U.S. Applications, 60/485,027, filed July 3, 2003 and 60/432,699, filed December 10, 2002

Claims 1-212 are pending.

It is noted that given the large number of claims and number of independent inventions within claims, that this was the best approximation that the Examiner determined to be independent inventions.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I-IV. Claims 2, 4, 5-19, drawn to a method of modulating expression of a THAP responsive gene, said method comprising modulating the interaction of a THAP-family polypeptide of a biologically active fragment thereof with a nucleic acid, thereby enhancing expression of said THAP gene, classified in class 536 subclass 23.1.

Each THAP-responsive promoter is unique as each has its specific biological activity and structure. Each is thus patentably distinct.

I. DR-5

II. ER-11

III.THRE

IV. THAP responsive promoter does not comprise a THAP responsive element

V-VIII. Claims 2, 4, 5-19, drawn to a method of modulating expression of a THAP responsive gene, said method comprising modulating the interaction of a THAP-

family polypeptide of a biologically active fragment thereof with a nucleic acid, thereby repressing expression of said THAP gene, classified in class 536, subclass 23.1 or class 530, subclass 350.

Each THAP-responsive promoter is unique as each has its specific biological activity and structure. Each is thus patentably distinct.

V. DR-5

VI. ER-11

VII.THRE

VIII. THAP responsive promoter does not comprise a THAP responsive element

IX-XVI. Claims 21, 23-37, drawn to a method of modulating the expression of a gene responsive to a THAP/chemokine complex, said method comprising modulating the interaction of a chemokine with a THAP-family polypeptide or a biologically active fragment thereof, thereby enhancing expression of said gene, classified in class 536, subclass 23.1, or class 530, subclass, 350.

Each chemokine is unique as each has a specific biological activity and structure.

IX. SLC

X. CCL19

XI. CCL5

XII.CXC11

XIII. CSCL10

XIV. CXCL9

XV-XX. Claims 21, 23-37, drawn to a method of modulating the expression of a gene responsive to a THAP/chemokine complex, said method comprising modulating the interaction of a chemokine with a THAP-family polypeptide or a biologically active fragment thereof, thereby repressing expression of said gene, classified in class 536, subclass 23.1, or class 530, subclass 350.

Each chemokine is unique as each has a specific biological activity and structure. Each is thus patentably distinct.

XV.SLC

XVI. CCL19

XVII. CCL5

XVIII. CXC11

XIX. CSCL10

XX. CXCL9

XXI-XLIV. Claims 39-58, drawn to a method of modulating the expression of a gene responsive to a THAP/chemokine complex, said method comprising modulating the interaction of a THAP/chemokine complex with a nucleic acid, thereby enhancing expression of said gene, classified in class 536, subclass 23.1, or class 530, subclass 350.

Each chemokine is unique as each has a specific biological activity and structure. Each THAP-responsive promoter is unique as each has its specific biological activity and structure. Each is thus patentably distinct.

XXI. DR5 and SCL

XXII. DR5 and CCL19

XXIII. DR5 and CCL5

XXIV. DR5 and CXCL11

XXV. DR5 and CXCL10

XXVI. DR5 and CXCL9

XXVII. ER11 and SCL

XXVIII. ER11 and CCL19

XXIX. ER11 and CCL5

XXX. ER11 and CXCL11

XXXI. ER11 and CXCL10

XXXII. ER11 and CXCL9

XXXIII. THRE and SCL

XXXIV. THRE and CCL19

XXXV. THRE and CCL5

XXXVI. THRE and CXCL11

XXXVII. THRE and CXCL10

XXXVIII. THRE and CXCL9

XXXIX. THAP responsive promoter that does not comprise a THAP responsive element and SCL

XL. THAP responsive promoter that does not comprise a THAP responsive element and CCL19

XLI. THAP responsive promoter that does not comprise a THAP r responsive element and CCL5

XLII. THAP responsive promoter that does not comprise a THAP responsive element and CXCL11

XLIII. THAP responsive promoter that does not comprise a THAP responsive element and CXCL10

XLIIV. THAP responsive promoter that does not comprise a THAP responsive element and CXCL9.

XLV-LXVIII. Claims 39-58, drawn to a method of modulating the expression of a gene responsive to a THAP/chemokine complex, said method comprising modulating the interaction of a THAP/chemokine complex with a nucleic acid, thereby repressing expression of said gene, classified in class 536, subclass 23.1, or class 530, subclass 350.

Each chemokine is unique as each has a specific biological activity and structure. Each THAP-responsive promoter is unique as each has its specific biological activity and structure. Each is thus patentably distinct.

XLV. DR5 and SCL

XLVI. DR5 and CCL19

XLVII. DR5 and CCL5

XLVIII. DR5 and CXCL11

XLIX. DR5 and CXCL10

L. DR5 and CXCL9

LI. ER11 and SCL

LII. ER11 and CCL19

LIII. ER11 and CCL5

LIV. ER11 and CXCL11

LV. ER11 and CXCL10

LVI. ER11 and CXCL9

LVII. THRE and SCL

LVIII. THRE and CCL19

LIX. THRE and CCL5

LX. THRE and CXCL11

LXI. THRE and CXCL10

LXII. THRE and CXCL9

LXIII. THAP responsive promoter that does not comprise a THAP responsive element and SCL

LXIV. THAP responsive promoter that does not comprise a THAP responsive element and CCL19

LXV. THAP responsive promoter that does not comprise a THAP responsive element and CCL5

LXVI. THAP responsive promoter that does not comprise a THAP responsive element and CXCL11

LXVII THAP responsive promoter that does not comprise a THAP responsive element and CXCL10

LXVIII. THAP responsive promoter that does not comprise a THAP responsive element and CXCL9.

LXIX-LXXI. Claims 60-62, drawn to a pharmaceutical composition comprising a THAP responsive element in a pharmaceutically acceptable carrier, classified in class 536, subclass 23.1.

Each THAP-responsive promoter is unique as each has its specific biological activity and structure. Each is thus patentably distinct.

LXIX. DR-5

LXX. ER-11

LXXI. THRE

LXXII-LXXIV. Claims 64-67, drawn to a transcription factor decoy and a cell comprising a transcription factor decoy, classified in class 536, subclass 23.1.

Each THAP-responsive promoter is unique as each has its specific biological activity and structure. Each is thus patentably distinct.

LXXII. DR-5

LXXIII. ER-11

LXXIV.THRE

LXXV-LXXVII. Claims 69-72, drawn to a method of modulating the interaction between a nucleic acid and a THAP-family polypeptide or a biologically active fragment thereof, said method comprising providing a transcription factor decoy which comprises a THAP responsive element, thereby modulating the interaction between said nucleic acid and said THAP-family polypeptide or a biologically

active fragment thereof, classified in class 536, subclass 23.1, or class 530, subclass 350.

Each THAP-responsive promoter is unique as each has its specific biological activity and structure. Each is thus patentably distinct.

LXXV. DR-5

LXXVI. ER-11

LXXVII.THRE

LXXVIII-XCV. Claims 74-80, drawn to a method of modulating the interaction between a nucleic acid and a THAP/chemokine complex, said method comprising providing a transcription factor decoy which comprises a THAP-responsive element, thereby modulating the interaction between said nucleic acid and said THAP/chemokine complex, classified in class 536, subclass 23.1, or class 530, subclass 350.

Each chemokine is unique as each has a specific biological activity and structure.

Each THAP-responsive promoter is unique as each has its specific biological activity and structure. Each is thus patentably distinct.

LXXVIII. DR5 and SCL

LXXIX. DR5 and CCL19

LXXX. DR5 and CCL5

LXXXI. DR5 and CXCL11

LXXXII. DR5 and CXCL10

LXXXIII. DR5 and CXCL9

LXXXIV. ER11 and SCL

LXXXV. ER11 and CCL19

LXXXVI. ER11 and CCL5

LXXXVII. ER11 and CXCL11

LXXXVIII. ER11 and CXCL10

LXXXIX. ER11 and CXCL9

XC. THRE and SCL

XCI. THRE and CCL19

XCII. THRE and CCL5

XCIII. THRE and CXCL11

XCIV. THRE and CXCL10

XCV. THRE and CXCL9

XCVI. Claims 87-97, drawn to a vector packaging cell line comprising a cell comprising a viral vector which comprises a promoter operably linked to a nucleic acid encoding a THAP-family polypeptide or a biologically active fragment thereof, classified in class 435, subclass 325

XCVII-CII. Claims 83, 85-91, drawn to a vector packaging cell line comprising a cell comprising a viral vector which comprises a promoter operably linked to a nucleic acid encoding a THAP-family polypeptide or a biologically active fragment thereof and wherein said cell further comprises a nucleic acid encoding a chemokine operably linked to a promoter, classified in class 435, subclass 325.

Each chemokine is unique as each has a specific biological activity and structure. Each is thus patentably distinct.

XCVII. SLC

XCVIII. CCL19

XCIX. CCL5

C. CXC11

CI. CSCL10

CII. CXCL9

CIII. Claims 105-110, drawn to a method of constructing a cell which expresses a recombinant THAP-family polypeptide, said method comprising introducing into a cell a vector comprising a nucleic acid encoding a THAP-family polypeptide or a biologically active fragment thereof operably linked to a promoter, classified in class 435, subclass 325.

CIV-CIX. Claims 100-110, drawn to a method of constructing a cell which expresses a recombinant THAP-family polypeptide, said method comprising introducing into a cell a vector comprising a nucleic acid encoding a THAP-family polypeptide or a biologically active fragment thereof operably linked to a promoter and wherein said cell further comprises a nucleic acid encoding a chemokine operably linked to a promoter, classified in class 435, subclass 325.

Each chemokine is unique and each has a specific biological activity and structure. Each is thus patentably distinct.

CIV. SLC

CV. CCL19

CVI. CCL5

CVII. CXC11

CVIII. CSCL10

CIX. CXCL9

CX-CXV. Claims 112-115, 117-119, drawn to a method of ameliorating symptoms associated with a condition mediated by a THAP/chemokine complex, said method comprising:

introducing into a cell a nucleic acid construct comprising a nucleic acid encoding a chemokine operably linked to a promoter and a nucleic acid construct comprising a nucleic acid encoding a THAP-family polypeptide or a biologically active fragment thereof operably linked to a promoter and

expressing said nucleic acid encoding said chemokine and said nucleic acid encoding said THAP-family polypeptide or biologically active fragment thereof, classified in class 435, subclass 325 or class 536, subclass 23.1.

Each chemokine is unique as each has a specific biological activity and structure. Each is thus patentably distinct.

CX.SLC

CXI. CCL19

CXII. CCL5

CXIII. CXC11

CXIV. CSCL10

CXV. CXCL9

CXVI. Claims 123, 124, drawn to a method of identifying a test compound that modulates transcription at a THAP-responsive element, said method comprising:

comparing the level of transcription from a THAP-responsive promoter in the presence and absence of a test compound wherein a determination that the level of transcription is increased in the presence of said test compound relative to the level of transcription in the absence of said test compound indicates that said test compound is a candidate modulator of transcription,

wherein level of transcription is determined by performing an in vitro transcription reaction, classified in class 536, subclass 23.1, or class 514, subclass 1.

CXVII. Claims 123, 124, drawn to a method of identifying a test compound that modulates transcription at a THAP-responsive element, said method comprising:

comparing the level of transcription from a THAP-responsive promoter in the presence and absence of a test compound wherein a determination that the level of transcription is decreased in the presence of said test compound relative to the level of transcription in the absence of said test compound indicates that said test compound is a candidate modulator of transcription,

wherein level of transcription is determined by performing an in vitro transcription reaction, classified in class 536, subclass 23.1, or class 514, subclass 1.

CXVIII. Claims 123, 124, drawn to a method of identifying a test compound that modulates transcription at a THAP-responsive element, said method comprising:

comparing the level of transcription from a THAP-responsive promoter in the presence and absence of a test compound wherein a determination that the level of transcription is increased in the presence of said test compound relative to the level of transcription in the absence of said test compound indicates that said test compound is a candidate modulator of transcription,

wherein level of transcription is determined by measuring the level of transcription from a THAP-responsive promoter in a cell, classified in class 536, subclass 23.1, or class 514, subclass 1.

CXIX. Claims 123, 124, drawn to a method of identifying a test compound that modulates transcription at a THAP-responsive element, said method comprising:

comparing the level of transcription from a THAP-responsive promoter in the presence and absence of a test compound wherein a determination that the level of transcription is decreased in the presence of said test compound relative to the level of transcription in the absence of said test compound indicates that said test compound is a candidate modulator of transcription,

wherein level of transcription is determined by measuring the level of transcription from a THAP-responsive promoter in a cell, classified in class 536, subclass 23.1 or class 514, subclass 1.

CXX- CXLIII. Claims 124, 123, 126-139, drawn to a method of identifying a test compound that modulates transcription at a THAP-responsive element, said method comprising:

comparing the level of transcription from a THAP-responsive promoter in the presence of a chemokine in the presence and absence of a test compound wherein a determination that the level of transcription is increased in the presence of said test compound relative to the level of transcription in the absence of said test compound indicates that said test compound is a candidate modulator of transcription,

wherein level of transcription is determined by performing an in vitro transcription reaction, classified in class 536, subclass 23.1, or class 514, subclass 1.

Each chemokine is unique as each has a specific biological activity and structure. Each THAP-responsive promoter is unique as each has its specific biological activity and structure. Each is thus patentably distinct.

CXX. DR5 and SCL

CXXI. DR5 and CCL19

CXXII. DR5 and CCL5

CXXIII. DR5 and CXCL11

CXXIV. DR5 and CXCL10

CXXV. DR5 and CXCL9

CXXVI. ER11 and SCL

CXXVII. ER11 and CCL19

CXXVIII. ER11 and CCL5

CXXIX. ER11 and CXCL11

CXXX. ER11 and CXCL10

CXXXI. ER11 and CXCL9

CXXXII. THRE and SCL

CXXXIII. THRE and CCL19

CXXXIV. THRE and CCL5

CXXXV. THRE and CXCL11

CXXXVI. THRE and CXCL10

CXXXVII. THRE and CXCL9

CXXXVIII. THAP responsive promoter that does not comprise a THAP responsive element and SCL

CXXXIX. THAP responsive promoter that does not comprise a THAP responsive element and CCL19

CXL. THAP responsive promoter that does not comprise a THAP responsive element and CCL5

CXLI. THAP responsive promoter that does not comprise a THAP responsive element and CXCL11

CXLII. THAP responsive promoter that does not comprise a THAP responsive element and CXCL10

CXLIII. THAP responsive promoter that does not comprise a THAP responsive element and CXCL9.

CXLIV- CLXVII. Claims 124, 123, 126-139, drawn to a method of identifying a test compound that modulates transcription at a THAP-responsive element, said method comprising:

comparing the level of transcription from a THAP-responsive promoter in the presence of a chemokine in the presence and absence of a test compound wherein a determination that the level of transcription is decreased in the presence of said test compound relative to the level of transcription in the absence of said test compound indicates that said test compound is a candidate modulator of transcription,

wherein level of transcription is determined by performing an in vitro transcription reaction, classified in class 536, subclass 23.1, or class 514, subclass 1.

Each chemokine is unique as each has a specific biological activity and structure. Each THAP-responsive promoter is unique as each has its specific biological activity and structure. Each is thus patentably distinct.

CXLIV. DR5 and SCL

CXLV. DR5 and CCL19

CXLVI. DR5 and CCL5

CXLVII. DR5 and CXCL11

CXLVIII. DR5 and CXCL10

CXLIX. DR5 and CXCL9

CL. ER11 and SCL

CLI. ER11 and CCL19

CLII. ER11 and CCL5

CLIII. ER11 and CXCL11

CLIV. ER11 and CXCL10

CLV. ER11 and CXCL9

CLVI. THRE and SCL

CLVII. THRE and CCL19

CLVIII. THRE and CCL5

CLIX. THRE and CXCL11

CLX. THRE and CXCL10

CLXI. THRE and CXCL9

CLXII. THAP responsive promoter that does not comprise a THAP responsive element and SCL

CLXIII. THAP responsive promoter that does not comprise a THAP responsive element and CCL19

CLXIV. THAP responsive promoter that does not comprise a THAP responsive element and CCL5

CLXV. THAP responsive promoter that does not comprise a THAP responsive element and CXCL11

CLXVI. THAP responsive promoter that does not comprise a THAP responsive element and CXCL10

CLXVII. THAP responsive promoter that does not comprise a THAP responsive element and CXCL9.

CLXVIII- CXCI. Claims 123, 124, 126-139, drawn to a method of identifying a test compound that modulates transcription at a THAP-responsive element, said method comprising:

comparing the level of transcription from a THAP-responsive promoter in the presence of a chemokine and in the presence and absence of a test compound wherein a determination that the level of transcription is increased in the presence of said test compound relative to the level of transcription in the absence of said test compound indicates that said test compound is a candidate modulator of transcription,

wherein level of transcription is determined by measuring the level of transcription from a THAP-responsive promoter in a cell, classified in class 536, subclass 23.1 or class 514, subclass 1.

Each chemokine is unique as each has a specific biological activity and structure. Each THAP-responsive promoter is unique as each has its specific biological activity and structure. Each is thus patentably distinct.

CLXVIII. DR5 and SCL

CLXIX. DR5 and CCL19

CLXX. DR5 and CCL5

CLXXI. DR5 and CXCL11

CLXXII. DR5 and CXCL10

CLXXIII. DR5 and CXCL9

CLXXIV. ER11 and SCL

CLXXV. ER11 and CCL19

CLXXVI. ER11 and CCL5

CLXXVII. ER11 and CXCL11

CLXXVIII. ER11 and CXCL10

CLXXIX. ER11 and CXCL9

CLXXX. THRE and SCL

CLXXXI. THRE and CCL19

CLXXXII. THRE and CCL5

CLXXXIII. THRE and CXCL11

CLXXXIV. THRE and CXCL10

CLXXXV. THRE and CXCL9

CLXXXVI. THAP responsive promoter that does not comprise a THAP responsive element and SCL

CLXXXVII. THAP responsive promoter that does not comprise a THAP responsive element and CCL19

CLXXXVIII. THAP responsive promoter that does not comprise a THAP responsive element and CCL5

CLXXXIX. THAP responsive promoter that does not comprise a THAP responsive element and CXCL11

CXC. THAP responsive promoter that does not comprise a THAP responsive element and CXCL10

CXCI. THAP responsive promoter that does not comprise a THAP responsive element and CXCL9.

CXCII- CCXV. Claims 123, 124, 126-139, drawn to a method of identifying a test compound that modulates transcription at a THAP-responsive element, said method comprising:

comparing the level of transcription from a THAP-responsive promoter in the presence of a chemokine and in the presence and absence of a test compound wherein a determination that the level of transcription is decreased in the presence of said test compound relative to the level of transcription in the absence of said test compound indicates that said test compound is a candidate modulator of transcription,

wherein level of transcription is determined by measuring the level of transcription from a THAP-responsive promoter in a cell, classified in class 536, subclass 23.1, or class 514, subclass 1.

Each chemokine is unique as each has a specific biological activity and structure. Each THAP-responsive promoter is unique as each has its specific biological activity and structure. Each is thus patentably distinct.

CXCII. DR5 and SCL

CXCIII. DR5 and CCL19

CXCIV. DR5 and CCL5

CXCV. DR5 and CXCL11

CXCVI. DR5 and CXCL10

CXCVII. DR5 and CXCL9

CXCVIII. ER11 and SCL

CXCIX. ER11 and CCL19

CC. ER11 and CCL5

CCI. ER11 and CXCL11

CCII. ER11 and CXCL10

CCIII. ER11 and CXCL9

CCIV. THRE and SCL

CCV. THRE and CCL19

CCVI. THRE and CCL5

CCVII. THRE and CXCL11

CCVIII. THRE and CXCL10

CCIX. THRE and CXCL9

CCX. THAP responsive promoter that does not comprise a THAP responsive element and SCL

CCXI. THAP responsive promoter that does not comprise a THAP responsive element and CCL19

CCXII. THAP responsive promoter that does not comprise a THAP responsive element and CCL5

CCXIII. THAP responsive promoter that does not comprise a THAP responsive element and CXCL11

CCXIV. THAP responsive promoter that does not comprise a THAP responsive element and CXCL10

CCXV. THAP responsive promoter that does not comprise a THAP responsive element and CXCL9.

CCXVI-CCXXI. Claims 141-146, drawn to a method for reducing the symptoms associated with a condition, comprising modulating the interaction between a THAP-familiy polypeptide and a chemokine in an individual suffereing from said condition, and a method for reducing symptoms associated with a condition resulting from the activity of a chemokine in an individual comprising modulating the interaction between said chemokine and a THAP-family polypeptide in an individual, classified in class 530, subclass 350.

Each chemokine is unique as each has a specific biological activity and structure. Each is thus patentably distinct.

CCXVI. SLC

CCXVII. CCL19

CCXVIII. CCL5

CCXIX. CXC11

CCXX. CSCL10

CCXXI. CXCL9

CCXXII-CCXXVII. Claims 148-157, drawn to a method for reducing the symptoms associated with a condition resulting from the activity of a chemokine in an individual comprising modulating the interaction between said chemokine and a THAP-family polypeptide in said indivudual, classified in class 530, subclass 350. Each chemokine is unique as each has a specific biological activity and structure. Each is thus patentably distinct.

CCXXII. SLC

CCXXIII. CCL19

CCXXIV. CCL5

CCXXV. CXC11

CCXXVI. CSCL10

CCXXVII. CXCL9

CCXXVIII-CCXXX. Claims 159-162, drawn to a method of reducing the symptoms associated with a condition resulting from the activity of a THAP-family polypeptide in an individual comprising modulating the extent of transcriptional repression of at least one THAP-family responsive promoter in said individual, classified in class 536, subclass 23.1.

Each THAP-responsive promoter is unique as each has its specific biological activity and structure. Each is thus patentably distinct.

CCXXVIII. DR-5

CCXXIX. ER-11

CCXXX.THRE

CCXXXI-CCXXXIII. Claims 159-162, drawn to a method of reducing the symptoms associated with a condition resulting from the activity of a THAP-family polypeptide in an individual comprising modulating the extent of transcriptional activation of at least one THAP-family responsive promoter in said individual, classified in class 536, subclass 23.1.

Each THAP-responsive promoter is unique as each has its specific biological activity and structure. Each is thus patentably distinct.

CCXXXI. DR-5

CCXXXII. ER-11

CCXXXIII.THRE

CCXXXIV-CCXXXIX. Claims 164-168, drawn to a method of reducing symptoms associated with a condition resulting from the activity of a THAP-family polypeptide in an individual, wherein a compound that modulates the interaction between a THAP-family polypeptide and a chemokine is administered to the individual, classified in class 514, subclass 1.

Each chemokine is unique as each has a specific biological activity and structure. Each is thus patentably distinct.

CCXXXIV. SLC

CCXXXV. CCL19

CCXXXVI. CCL5

CCXXXVII. CXC11

CCXXXVIII. CSCL10

CCXXXIX. CXCL9

CCXL-CCXLV. Claims 170, 171, 173, 174, drawn to a method of reducing symptoms associated with a condition resulting from the activity of a THAP-family polypeptide in an individual, wherein a chemokine or an analog thereof is administered to an individual, classified in class 530, subclass 350.

Each chemokine is unique as each has a specific biological activity and structure. Each is thus patentably distinct.

CCXL. SLC

CCXLI. CCL19

CCXLII. CCL5

CCXLIII. CXC11

CCXLIV. CSCL10

CCXLV. CXCL9

CCXLVI-CCLI. Claims 176-180, drawn to a method of reducing symptoms associated with transcriptional repression mediated by a THAP-family polypeptide in an individual comprising administering a chemokine or analog thereof to said individual, classified in class 530, subclass 350.

CCXLVI. SLC

CCXLVII. CCL19

CCXLVIII. CCL5

CCXLIX. CXC11

CCL. CSCL10

CCLI. CXCL9

CCLII-CCLVI. Claims 176-180, drawn to a method of reducing symptoms associated with transcriptional activation mediated by a THAP-family polypeptide in an individual comprising administering a chemokine or analog thereof to said individual, classified in class 530, subclass 350.

Each chemokine is unique as each has a specific biological activity and structure. Each is thus patentably distinct.

CCLII. SLC

CCLIII. CCL19

CCLIV. CCL5

CCLV. CXC11

CCLVI. CSCL10

CCLVII. CXCL9

CCLVIII-CCLXIII. Claims 182-189, drawn to a method of reducing the symptoms associated with the activity of a chemokine in an individual comprising modulating the extent to which said chemokine is transported to the nucleus of a cell in an individual, classified in class 530, subclass 350.

CCLVIII. SLC

CCLIX. CCL19

CCLX. CCL5

CCLXI. CXC11

CCLXII. CSCL10

CCLXIII. CXCL9

CCLXIV-CCLXIX. Claims 191-199, drawn to a method for identifying a compound which modulates the transport of a chemokine into the nucleus comprising comparing the extent of said chemokine transport into the nucleus of cells in the presence and absence of a test compound, classified in class 530, subclass 350, or class 514, subclass 1.

Each chemokine is unique as each has a specific biological activity and structure. Each is thus patentably distinct.

CCLXIV. SLC

CCLXV. CCL19

CCLXVI. CCL5

CCLXVII. CXC11

CCLXVIII. CSCL10

CCLXIX. CXCL9

CCLXX. Claims 200-201, 203, drawn to a vector comprising a THAP-responsive promoter operably linked to a nucleic acid encoding a detectable product, wherein the THAP-responsive promoter comprises a THAP responsive element, and to a cell comprising said vector, classified in class 514, subclass 44.

CCLXXI. Claims 200, 202, 203, drawn to a vector comprising a THAP-responsive promoter operably linked to a nucleic acid encoding a detectable product, wherein the THAP-responsive promoter does not comprise a THAP responsive

element, and to a cell comprising said vector, classified in class 514, subclass 44.

CCLXXII. Claims 204-205, drawn to an *in vitro* transcription reaction comprising a nucleic acid comprising a THAP responsive promoter, ribonucleotides, and an RNA polymerase, classified in class 536, subclass 23.1.

CCLXXIII-CCLXXVIII. Claims 207-212, drawn to an isolated mutant THAP-family polypeptide that does not bind to a chemokine, classified in class 530, subclass 350.

Each chemokine is unique as each has a specific biological activity and structure. Each is thus patentably distinct.

CCLXXIII. SLC

CCLXXIV. CCL19

CCLXXV. CCL5

CCLXXVI. CXC11

CCLXXVII. CSCL10

CCLXXVIII. CXCL9

The inventions are distinct, each from the other because of the following reasons:

Claims 1 and 3 link(s) inventions I-VIII.

Claims 20 and 22 link(s) inventions IX-XX.

Claim 38 link(s) inventions XXI-LXVIII.

Claim 59 link(s) inventions LXIX-LXXI.

Claim 63 link(s) inventions LXXII-LXXIV.

Claim 68 link(s) inventions LXXV-LXXVII.

Claim 73 link(s) inventions LXXVIII-XCV.

Claim 81 link(s) inventions XCVI-CII.

Claims 82 and 84 link(s) inventions XCVII-CII.

Claim 98 link(s) inventions CIV-CIX.

Claim 99 link(s) inventions CV-CIX.

Claim 111 link(s) inventions CX-CXV.

Claim 120 link(s) inventions CXVI-CLXV.

Claim 121 link(s) inventions CXVI, CXVIII-CXLI.

Claim 125 link(s) inventions CXVIII-CXLI and CXLII-CLXV.

Claim 140 link(s) inventions CLXVI-CLXXI.

Claim 147 link(s) inventions CLXXII-CLXXXIII.

Claim 158 link(s) inventions CLXXVIII-CLXXX.

Claim 163 link(s) inventions CLXXXIV-CLXXXIX.

Claims 169 and 172 link(s) inventions CXC-CXCV.

Claim 175 link(s) inventions CXCVI-CCVII.

Claim 181 link(s) inventions CCVII-CCXIII.

Claim 190 link(s) inventions CCXIV-CCXIX.

Claim 206 link(s) inventions CCXXIII-CCXXVIII.

The restriction requirement amongst the linked inventions is subject to the nonallowance of the linking claim(s), claims 1, 3, 20, 22,38, 59, 63, 68, 73, 81, 82, 84, 98, 99, 111, 120, 121, 125, 140, 147, 158, 163, 175, 181, 190, 206. Upon the

allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Inventions I-IV and V-VIII are patentably distinct. While these inventions are similarly drawn to a method of modulating expression of a THAP-responsive gene comprising modulating the interaction of a THAP-family protein and a nucleic acid, Inventions I-IV involve enhancing expression of a THAP-responsive gene, while Inventions V-VIII involved repressing expression of a THAP-responsive gene. These are opposite effects. The searches for Inventions I-IV and V-VIII are burdensome because the searches are not coextensive.

Inventions IX-XVI and XV-XX are patentably distinct. While these inventions are similarly drawn to a method of modulating the interaction between a chemokine and a THAP-family polypeptide or a biologically active fragment, thereof, Inventions IX-XVI involve enhancing expression of a THAP-responsive gene, while Inventions XV-XX

involve repressing expression of a THAP-responsive gene. These are opposite effects. The searches for Inventions IX-XVI and XV-XX are burdensome because the searches are not coextensive.

Inventions XXI-XLIV and XLV-LXVIII are patentably distinct. While these inventions are similarly drawn to a method of modulating the interaction between a chemokine and a THAP-family polypeptide or a biologically active fragment, thereof, Inventions XXI-XLIV involve enhancing expression of a THAP-responsive gene, while Inventions XLV-LXVIII involve repressing expression of a THAP-responsive gene. These are opposite effects. The searches for Inventions XXI-XLIV and XLV-LXVIII are burdensome because the searches are not coextensive.

Inventions I-IV/V-VIII, IX-XVI/XV-XX, and XXI-XLIV/XLV-LXVIII are patentably distinct. Inventions I-IV/V-VIII are distinct from Inventions IX-XVI/XV-XX and XXI-XLIV/XLV-LXVIII because inventions involve modulating expression of a gene, between a THAP-family protein and a nucleic acid. Inventions IX-XVI/XV-XX and XXI-XLIV/XLV-LXVIII additionally involve a chemokine. Inventions IX-XVI/XV-XX and XXI-XLIV/XLV-LXVIII are distinct from each other because Inventions XXI-XLIV/XLV-LXVIII are specifically drawn to modulating the interaction between the protein complex and a nucleic acid, while Inventions IX-XVI/XV-XX is drawn to modulating the interaction between the chemokine and the THAP-family polypeptide. The search for Inventions I-LXVIII are burdensome because the searches are not coextensive.

Inventions LXIX-LXXI are patentably distinct from Inventions LXXII-LXXIV because while both inventions are drawn to nucleic acids comprising a THAP-responsive element, their intended uses are different. Inventions LXIX-LXXI are drawn to using the nucleic acids as a pharmaceutical compound, whereas Inventions LXXII-LXXIV are drawn to using the nucleic acids as a transcription factor decoy, which does not necessarily entail that the nucleic acid has a therapeutic use. The searches for Inventions LXIX-LXXIV are burdensome because the searches are not coextensive.

Inventions LXXV-LXXVII and LXXVIII-XCV are patentably distinct from each other because while both methods are to modulating the interaction between a nucleic acid and a THAP-family polypeptide using a transcription factor decoy, Inventions LXXVIII-XCV additionally comprise a chemokine. The searches for Inventions LXV-XCV are burdensome because the searches are not coextensive.

Inventions LXIX-XCV are patentably distinct from each other. Invention LXIX-LXXI is drawn to a nucleic acid that is a pharamaceutical compound, whereas the intended use of the nucleic acids and method of using the nucleic acid as a transcription factor decoy of Inventions LXII-XCV do not necessarily have this required use. The searches for LXIX-XCV are burdensome because the searches are not coextensive.

Inventions XCVI and XCVII-CII are patentably distinct because while the Inventions are similarly drawn to a vector packaging cell line comprising a viral vector which comprises a promoter operably linked to a nucleic acid encoding a THAP-family polypeptide, Inventions XCVII-CII further comprise that the cell line express a

chemokine. The searches for Inventions XCVI-CII are burdensome because the searches are not coextensive.

Inventions XCVI-CII and CIII-CIX are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the method of making a packaging cell line that expresses a THAP-family polypeptide and the chemokine SLC, can also be used to make a packaging cell line that expresses a THAP-family polypeptide and the chemokine CCL19.

Inventions CXVI-CCXV are patentably distinct from each other because while these are methods of identifying a test compound that modulates transcription at a THAP-responsive element, Inventions CXVI, CXVII, CXX-CXLIII, CXLIV-CLXVII involve performing an in vitro transcription reaction, whereas Inventions CXVIII, CXIX, CLXVIII-CXCI, CXCII-CCXV involve measuring the level of transcription from a THAP-responsive promoter. These are two different ways of measuring transcription and require different steps. Inventions CXVI, CXVIII, CXX-CXLIII, CLXVIII-CXCI are distinct from Inventions CXVII, CXIX, CXLIV-CLXVII, and CXCII-CCXV because these Inventions identify compounds that increase the level of transcription, whereas the other Inventions identify compounds that decrease the level of transcription. Inventions CXVI-

CXIX are distinct from Inventions CXX-CCXV as CXX-CCXV require the presence of chemokines, whereas CXVI-CXIX do not.

Inventions CX-CXV, CCXVI-CCLXIII are patentably distinct from each other. While these are similar in that they are methods of reducing or ameliorating symptoms, Inventions CX-CXV are drawn to expressing a chemokine and a THAP-family polypeptide. This is distinct from the other Inventions because no other Inventions involve exogenous expression of chemokine and a THAP-family member to treat a symptom. CCXVI-CCXXVII are drawn to modulating an interaction between a THAP-family polypeptide and a chemokine. These Inventions are distinct from the other Inventions because they involve modulating the interaction between two proteins. It is noted that Inventions CCXVI-CCXXI are distinct from Inventions CCXXII-CCXXVII because while they are both drawn to modulating the interaction between a chemokine and a THAP-family polypeptide, Inventions CCXXII-CCXXVII require that the symptom is caused by the activity of a chemokine and a THAP-family polypeptide. CCXXVIII-CCXXX are drawn to modulating the extent of transcriptional repression of at least one THAP-family responsive promoter; CCXXXI-CCXXXIII is drawn to modulating the extent of transcriptional activation. These Inventions are distinct from each other because one set is drawn to repressing transcription; the other is drawn to activating transcription. These are two different effects. The Inventions are distinct from other Inventions because they involve transcriptional regulation to treat the symptoms. CCXXXIV-CCXXXIX is drawn to administering a compound that modulates the interaction between

a THAP-family polypeptide and a chemokine. These Inventions are distinct from Inventions CCXVI-CCXXVII, as the CCXXXIV-CCXXXIX require that a compound be used. CCXL-CCXLV is drawn to administering a chemokine or an analog, CCXLVI-CCLI are drawn to administering a chemokine or an analog, wherein administration of a chemokine or analog results in transcriptional repression mediated by a THAP-family polypeptide, and CCLIII-CCLVI are drawn to administering a chemokine or an analog, wherein administration of a chemokine or an analog results in transcriptional activation. These methods are distinct from the other methods because they comprise administering only a chemokine to treat the symptoms. These methods are distinct from each other as one set does not require that transcription be modulated, and while the other two sets require that the chemokine modulate transcription, one regulates activation and the other regulates repression, which are two different effects. CCLVIII-CCLXIII are drawn to modulating the extent to which a chemokine is transported to the nucleus of a cell. These methods are distinct from the other methods as none are drawn to modulating chemokine transportation into a nucleus. The searches for CIV-CIX, CCXVI-CCLXIII is burdensome because the searches are not coextensive.

CCLXX and CCLXXI are patentably distinct. While both are vectors comprising a THAP-responsive promoter, Invention CCLXX comprises a promoter comprising a THAP-responsive element, which means that the THAP/chemokine complex interacts with the THAP-responsive element directly. The vector that does not comprise a THAP-

responsive element interacts with the THAP/chemokine complex indirectly, such as in a biological response following a cascade of events.

Inventions I-XCV are patentably distinct. Inventions I-LXVIII are generally drawn to methods of modulating a THAP-responsive gene and Inventions LXIX-XCV are generally drawn to nucleic acids comprising a THAP responsive element and to using these nucleic acids in methods that modulate interactions between a nucleic acid, a THAP-family polypeptide, and a chemokine. Inventions I-LXVIII are similar to Inventions LXIX-XCV because they involve the interactions between a THAP-responsive element, a THAP-family polypeptide, and a chemokine. Inventions I-LXVIII remain distinct from Inventions LXIX-XCV because aside from using nucleic acids to modulate the interaction between a THAP/chemokine complex or THAP polypeptide and a nucleic acid, an artisan could use a chemical compound or another polypeptide.

Inventions I-XCV and XCVI-CIX are patentably distinct. Inventions I-LXVIII are generally drawn to methods of modulating a THAP-responsive gene. Inventions XCVI-CIX are generally drawn to a vector packaging cell line and to the methods of making said cell line. While Inventions I-LXVIII could use the cell lines to study *in vitro* interactions between THAP, a chemokine, and a THAP-responsive element, an artisan could do the study *in vitro* by using just the proteins and DNA (e.g. electrophoretic mobility shift assays (EMSA)).

Inventions I-XCV and CXVI-CCXV are patentably distinct. Inventions I-LXVIII are generally drawn to methods of modulating a THAP-responsive gene. Inventions CXVI-

CCXV are generally drawn to methods of identifying a test compound that modulates transcription at a THAP-responsive element. Inventions I-XLVIII depend on Inventions CXVI-CCXV for compounds that modulate a THAP-responsive gene.

Inventions I-XCV and CX-CXV/CCXVI-CCLXIII are patentably distinct. Inventions I-LXVIII are generally drawn to methods of modulating a THAP-responsive gene. Inventions CX-CXV and CCXVI-CCLXIII are generally drawn to methods of treating symptoms comprising either administering a chemokine and/or THAP-family polypeptide, altering the level of transcription regulated by a THAP-family polypeptide, or altering the amount of chemokine that enters a cell nucleus. While the Inventions are similar, Inventions CX-CXV/CCXVI-CCLXIII require that the method have therapeutic effects.

Inventions I-XCV and CCLXX/CCLXXI are patentably distinct. Inventions I-LXVIII are generally drawn to methods of modulating a THAP-responsive gene. Inventions CCLXX/CCLXXI are vectors comprising a THAP-responsive promoter. While one of the elements to which the methods of modulating a THAP-responsive gene involves the nucleic acid binding site, the method could also involve modulating the interaction between the chemokine and THAP.

Inventions I-XCV and CCLXXII are patentably distinct. Inventions I-LXVIII are generally drawn to methods of modulating a THAP-responsive gene. Invention CCLXXII is drawn to an *in vitro* transcription reaction comprising a nucleic acid comprising a THAP responsive promoter, ribonucleotides, and an RNA polymerase. While an *in vitro* transcription reaction may be a readout for determining the interaction

between a THAP-responsive promoter and a chemokine and a THAP-polypeptide, an artisan could also use a electophoretic mobility shift-assay (EMSA) to determine the interaction between proteins and DNA.

Inventions I-XCV and CCLXXIII-CCLXXVIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case Inventions I-LXVIII are generally drawn to methods of modulating a THAP-responsive gene. Inventions CCLXXIII-CCLXXVIII are drawn to an isolated mutant THAP-family polypeptide. Inventions I-LXVIII do not depend on Inventions CCLXXIII-CCLXXVIII to function and vice versa.

Inventions LXIX-XCV and XCVI-CIX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, Inventions LXIX-XCV are generally drawn to nucleic acids comprising a THAP responsive element and to using these nucleic acids in methods that modulate interactions between a nucleic acid, a THAP-family polypeptide, and a chemokine. Inventions XCVI-CIX are generally drawn to a vector packaging cell line and to the methods of making said cell line. The nucleic acids in Inventions LXIX-XCV are not used in making the cells of Inventions XCVI-CIX. Inventions LXIX-XCV do not depend on Inventions XCVI-CIX and vice versa.

Inventions LXIX-XCV and CXVI-CCXV are patentably distinct. Inventions LXIX-XCV are generally drawn to nucleic acids comprising a THAP responsive element and to using these nucleic acids in methods that modulate interactions between a nucleic acid, a THAP-family polypeptide, and a chemokine. Inventions CXVI-CCXV are generally drawn to methods of identifying a test compound that modulates transcription at a THAP-responsive element. While the nucleic acids of Inventions LXIX-XCV could be test compounds that modulate transcription at a THAP-responsive element, other compounds that could have the same function are proteins and chemical compounds.

Inventions LXIX-XCV and XC-XCV and CCXVI-CCLXIII are patentably distinct. Inventions LXIX-XCV are generally drawn to nucleic acids comprising a THAP responsive element and to using these nucleic acids in methods that modulate interactions between a nucleic acid, a THAP-family polypeptide, and a chemokine. Inventions CX-CXV and CCXVI-CCLXIII are generally drawn to methods of treating symptoms comprising either administering a chemokine and/or THAP-family polypeptide, altering the level of transcription regulated by a THAP-family polypeptide, or altering the amount of chemokine that enters a cell nucleus. While the nucleic acids of Inventions LXIX-XCV could be used in XC-XCV and CCXVI-CCLXIII, other compounds such as chemokines or other chemical compounds could also be used.

Inventions LXIX-XCV and CCLXX/CCLXXI are patentably distinct. Inventions LXIX-XCV are generally drawn to nucleic acids comprising a THAP responsive element and to using these nucleic acids in methods that modulate interactions between a nucleic acid, a THAP-family polypeptide, and a chemokine. Inventions CCLXX/CCLXXI

are vectors comprising a THAP-responsive promoter. While the nucleic acids comprising a THAP-responsive element could comprise the promoters of Inventions CCLXX/CCLXXI, the nucleic acids could also be supplied as fragments, not necessarily in a vector.

Inventions LXIX-XCV and CCLXII are patentably distinct. Inventions LXIX-XCV are generally drawn to nucleic acids comprising a THAP responsive element and to using these nucleic acids in methods that modulate interactions between a nucleic acid, a THAP-family polypeptide, and a chemokine. Invention CCLXXII is drawn to an *in vitro* transcription reaction comprising a nucleic acid comprising a THAP responsive promoter, ribonucleotides, and an RNA polymerase. While the Inventions of LXIX-XCV could be used in Invention CCLXII, other compounds such as proteins or a chemical compound could be used in Invention CCLXXII.

Inventions LXIX-XCV and CCLXXIII-CCLXXVIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, Inventions LXIX-XCV are generally drawn to nucleic acids comprising a THAP responsive element and to using these nucleic acids in methods that modulate interactions between a nucleic acid, a THAP-family polypeptide, and a chemokine. Inventions CCLXXIII-CCLXXVIII are drawn to an isolated mutant THAP-family polypeptide. Inventions LXIX-XCV do not depend on Inventions CCLXXIII-CCLXXVIII to function and vice versa.

Inventions XCVI-CIX and CXVI-CCXV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, Inventions XCVI-CIX are generally drawn to a vector packaging cell line and to the methods of making said cell line. Inventions CXVI-CCXV are generally drawn to methods of identifying a test compound that modulates transcription at a THAP-responsive element. Inventions XCVI-CIX do not comprise any THAP-responsive element and thus would not be used in the Inventions of CXVI-CCXV. Inventions XCIV-CIX do not depend on Inventions CXVI-CCXV.

Inventions XCVI-CIX and CX-CXV/CCXVI-CCLXIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, Inventions XCVI-CIX are generally drawn to a vector packaging cell line and to the methods of making said cell line. Inventions CX-CXV and CCXVI-CCLXIII are generally drawn to methods of treating symptoms comprising either administering a chemokine and/or THAP-family polypeptide, altering the level of transcription regulated by a THAP-family polypeptide, or altering the amount of chemokine that enters a cell nucleus. Inventions CX-CXV/CCXVI-CCLXIII require treating a condition by modulating a THAP-responsive element, a THAP-family polypeptide, and a chemokine. The cells of Inventions XCVI-CIX do not comprise a THAP-responsive element.

Inventions CXVI-CCXV and CX-CXV/CCXVI-CCLXIII are patentably distinct. Inventions CXVI-CCXV are generally drawn to methods of identifying a test compound that modulates transcription at a THAP-responsive element. Inventions CX-CXV and CCXVI-CCLXIII are generally drawn to methods of treating symptoms comprising either administering a chemokine and/or THAP-family polypeptide, altering the level of transcription regulated by a THAP-family polypeptide, or altering the amount of chemokine that enters a cell nucleus. While the compounds identified in Inventions CXVI-CCXV may be used in therapy, some identified may not have any therapeutic effects. Also, with regards to those compounds identified by Inventions CXVI-CCXV, while they might have therapeutic effects, an artisan would need to find the ideal conditions at which the compounds would work. These require distinct method steps which are not required in Inventions CXVI-CCXV.

Inventions CXVI-CCXV and CCLXX/CCLXXI are patentably distinct. Inventions CXVI-CCXV are generally drawn to methods of identifying a test compound that modulates transcription at a THAP-responsive element. Inventions CCLXX/CCLXXI are vector comprising a THAP-responsive promoter. While the vector comprising a THAP-responsive promoter could be used in Inventions CSVI-CCXV, other compounds, such as proteins or chemical compounds could be used.

Inventions CXVI-CCXV and CCLXXII are patentably distinct. Inventions CXVI-CCXV are generally drawn to methods of identifying a test compound that modulates transcription at a THAP-responsive element. Invention CCLXXII is drawn to an *in vitro* transcription reaction comprising a nucleic acid comprising a THAP responsive

promoter, ribonucleotides, and an RNA polymerase. While the transcription reaction of CCLXXII is one assay that could be used in Inventions CXVI-CCXV, other methods of identifying test compounds (such as EMSA) could be used.

Inventions CXVI-CCXV and CCLXXIII-CCLXXVIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, Inventions CXVI-CCXV are generally drawn to methods of identifying a test compound that modulates transcription at a THAP-responsive element. Inventions CCLXXIII-CCLXXVIII are drawn to an isolated mutant THAP-family polypeptide. Inventions CXVI-CCXV do not depend on Inventions CCLXXIII-CCLXXVIII and vice versa.

Inventions CCLXX/CCLXXI are patentably distinct from Invention CCLXXII. Inventions CCLXX/CCLXXI are vectors comprising a THAP-responsive promoter. Invention CCLXXII is drawn to an *in vitro* transcription reaction comprising a nucleic acid comprising a THAP responsive promoter, ribonucleotides, and an RNA polymerase. While CCLXX/CCLXXI could be used in the *in vitro* transcription reaction of CCLXXII, the vector could also be used in other applications, such as expressing a transgene of interest in a cell.

Inventions CCLXX/CCLXXI and CCLXXIII-CCLXXVIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case Inventions CCLXX/CCLXXI are

vectors comprising a THAP-responsive promoter. Inventions CCLXXIII-CCLXXVIII are drawn to an isolated mutant THAP-family polypeptide. Inventions CCLXX/CCLXXI do not require Invention CCLXXIII/CCLXXVIII to function and vice versa.

Inventions CCLXXII and CCLXXIII-CCLXXVIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, Invention CCLXXII is drawn to an *in vitro* transcription reaction comprising a nucleic acid comprising a THAP responsive promoter, ribonucleotides, and an RNA polymerase. Inventions CCLXXIII-CCLXXVIII are drawn to an isolated mutant THAP-family polypeptide. Invention CCLXXII does not require CCLXXIII-CCLXXVIII to function and vice versa.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, recognized divergent subject matter, and the search for one group is not required for another, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention:

Claims 1-10 of Invention I-VIII are generic for a THAP-responsive gene. The genes are:

1. Survivn

2. PTTG-1/Securin,

3. PTTG2/Secuin,

4. PTTG3/Securin,

5. CKS1,

6. MAD2L1,

7. USP16/Ubp-M,

8. HMMR/RHAMM

9. KIAA0008/HURP,

10. CDCA7/JPO1,

11. THAP1,

12. encodes a polypeptide involved in the G2 or M phase of the cell cycle,

13. encodes a polypeptide involved in the S phase of the cell cycle,

14. encodes a polypeptide involved in DNA replication,

15. encodes a polypeptide involved in DNA repair,

16. encodes a polypeptide involved RNA splicing,

17. encodes a polypeptide involved in apoptosis,

18. encodes a polypeptide involved in angiogenesis,

19. encodes a polypeptide involved proliferation of cancer cells

20. encodes a polypeptide involved in inflammatory disease.

Claims 20-28 of Inventions IX-XVI, and claims 38-42, 52-58 of Inventions XXI-LXVIII are generic for a THAP-responsive gene.

a1. encodes a polypeptide involved in the G2 or M phase of the cell cycle,

a2. encodes a polypeptide involved in the S phase of the cell cycle,

a3. encodes a polypeptide involved in DNA replication,

a4. encodes a polypeptide involved in DNA repair,

a5. encodes a polypeptide involved RNA splicing,

a6. encodes a polypeptide involved in apoptosis,

a7. encodes a polypeptide involved in angiogenesis,

a8. encodes a polypeptide involved proliferation of cancer cells

a9. encodes a polypeptide involved in inflammatory disease.

Claims 20-26, 29-37 of Inventions IX-XVI, claims 147-155 of Inventions CCXXII-CCXXVII, claims 181-187 of Inventions CCLII-CCLVI, claims 190-196,199 of Inventions CCLXIV-CCLXIX are generic for a THAP-type chemokine binding agent.

b1. THAP1 polypeptide,

b2. a chemokine-binding domain of aTHAP1 polypeptide,

b3. a THAP1 polypeptide oligomer,

b4. a chemokine-binding domain of a THAP1 polypeptide,

b5. a THAP1 polypeptide oligomer,

b6. an oligomer comprising a THAP1 chemokine binding domain,

b7. a THAP chemokine-ginding domain –immunoglobulin fusion.

Claims 120, 121,123,124 of Inventions CXVI-CXIX, claims 121,123-139,120,122,123,139 of Inventions CXX-CCXV, claims 140-146 of Inventions CCXVI-CCXXI, claims 158-159,161-162 of Inventions CCXXVIII-CCXXX are generic for a THAP family polypeptide of SEQ ID NO. 1-114. One SEQ ID NO. must be elected.

Claims 120, 121,123,124 of Inventions CXVI-CXIX, claims 121,123-139,120,122,123,139 of Inventions CXX-CCXV are generic for a THAP-responsive

element of SEQ ID NO. 140-159, 306.

Claims 140-142, 144, 146 of Inventions CCXVI-CCXXI are generic for symptoms associated with a condition:

c1. excessive angiogenesis,

c2. insufficient angiogenesis,

c3. inflammation,

c4. metastasis of cancerous tissue,

c5. excessive apoptosis,

c6. insufficient apoptosis,

c7. cardiovascular disease,

c8. neurodegenerative diseases

Claims 147-151, 153-157 of Inventions CCXXII-CCXXVII are generic for a symptoms associated with a condition.

d1. inflammation,

d2. excessive angiogenesis,

d3. insufficient angiogenesis

Claims 181-183, 186-189 of Inventions CCLVIII-CCLXIII and claims 190-192, 195-199 of Inventions CCLXIV-CCLXIX are generic for a chemokine receptor. Upon election of a chemokine, Applicant must elect a corresponding receptor to which the chemokine binds.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise

include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply

where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joanne Hama, Ph.D. whose telephone number is 571-272-2911. The examiner can normally be reached Monday through Thursday and alternate Fridays from 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, Ph.D. can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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JH

DAVE TRONG NGUYEN
SUPERVISORY PATENT EXAMINER